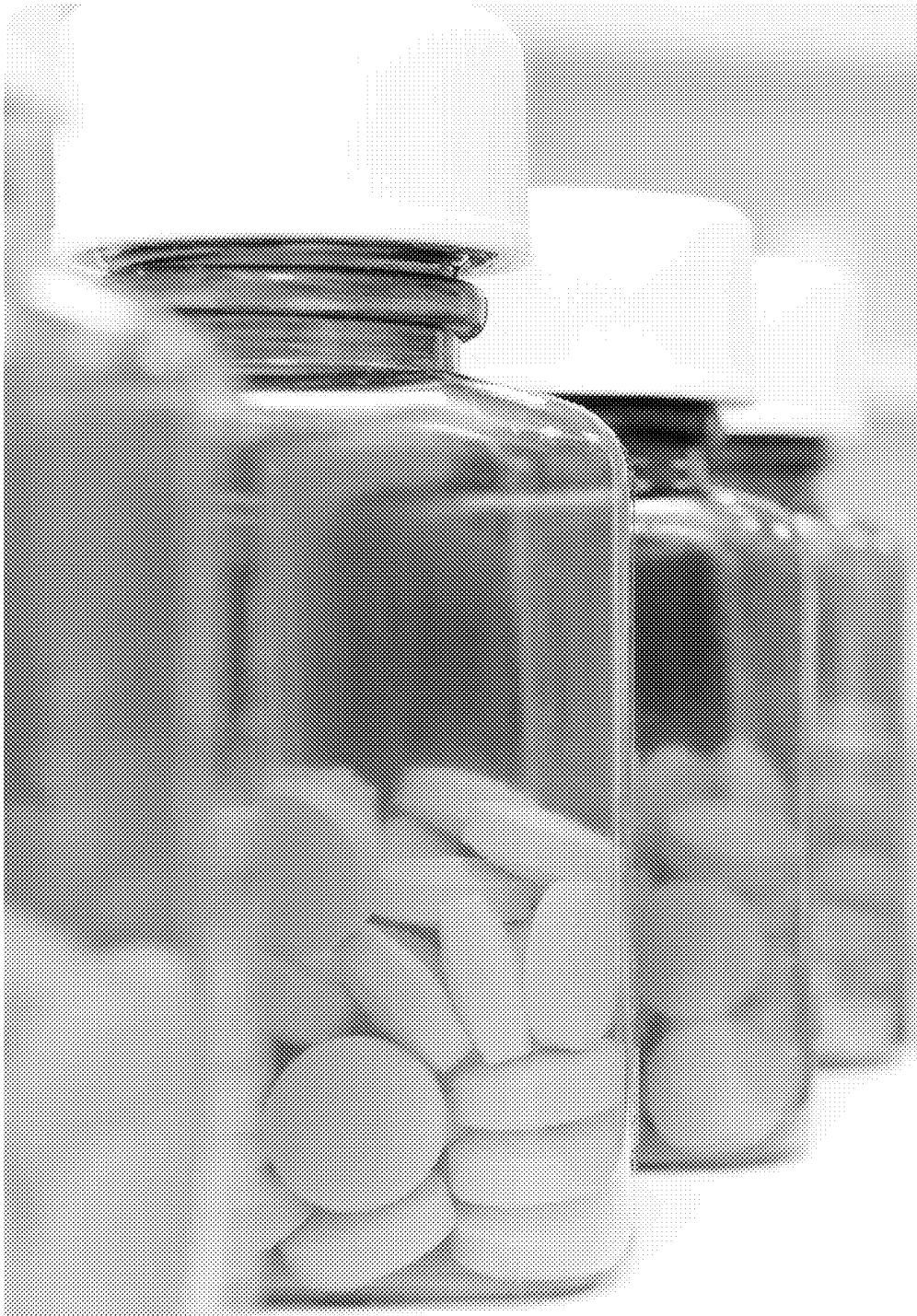
PSJ3

Exhibit 440



CRISIS PLAYBOOK

An Interactive Guide to Crisis Communications

CLICK TO LAUNCH PLAYBOOK ▸

CHDMA

Crisis Quick Reference Information

Core Crisis Team

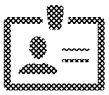
NAME	TITLE	EMAIL	OFFICE PHONE	CELL PHONE
John Gray	President and CEO	[redacted]		
Liz Gallenagh	VP, Government Affairs and General Counsel			
John Parker	VP, Communications			
Anita Ducca	VP, Regulatory Affairs			
Patrick Kelly	SVP, Government Affairs			
Perry Fri	SVP, Industry Relations, Membership & Education			

Executive Committee

NAME	COMPANY	EMAIL	OFFICE PHONE	CELL PHONE
David Neu	AmerisourceBergen	[redacted]		
Ted Scherr	Dakota Drug			
Ken Couch	Smith Drug			
Mike Kaufmann	Cardinal Health			
David Moody	Mutual Drug			
Dale Smith	H. D. Smith			
Paul Julian	McKesson			

Playbook Objectives

Provide **clear guidelines** for classifying crisis situations.



Define **roles and responsibilities** in a crisis situation.

Create an easy-to-use, step-by-step **crisis response protocol.**

Establish **a process to learn** from each incident and refine procedures for the future.

Initiate **ongoing monitoring system** for potential issues.

Have **ready-to-use response materials** on hand for high risk scenarios.

Crisis Communications Guiding Principles

Honesty and transparency are paramount.
At all times, strive to provide accurate and timely information, and communicate as much information as possible with the appropriate stakeholders.

Get the facts first.
Determine the facts, then build the communications strategy, and only provide information that you know is true and accurate.

Communicate early.
Getting ahead of an issue, or getting your message across as early as possible, is almost always the best way to minimize damage from a negative event.

Communicate frequently.
Refusing to offer information or a comment to media or other stakeholders, especially in response to direct questions, generally causes problems rather than prevents them.

Time is of the essence.
During a rapidly developing situation, it is critical to move quickly and efficiently, by minimizing churn and working as a team.

Express emotion appropriately.
The public demands more than the letter of the law or minimum adherence to regulations.

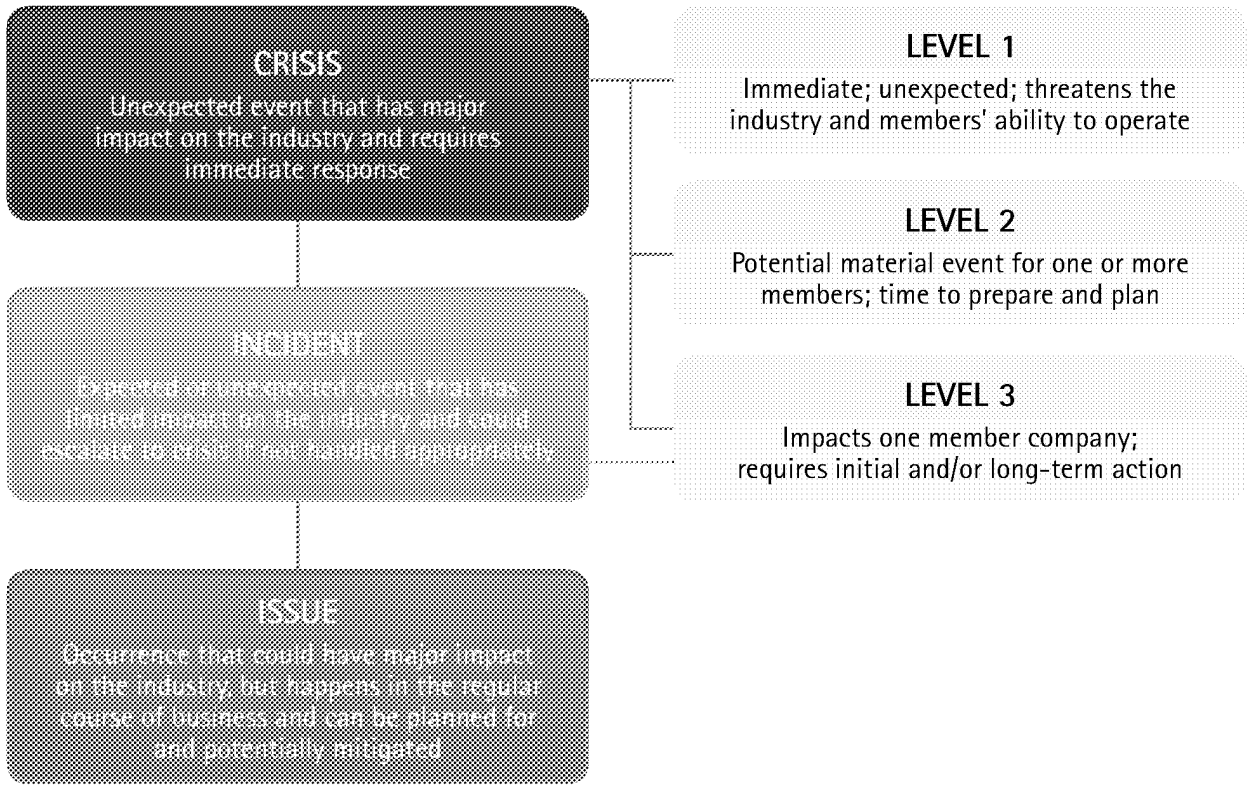
Address key stakeholders directly.
Getting stakeholders to give you the "benefit of the doubt" in a crisis can head off lasting reputation impact.

Incident Classification System

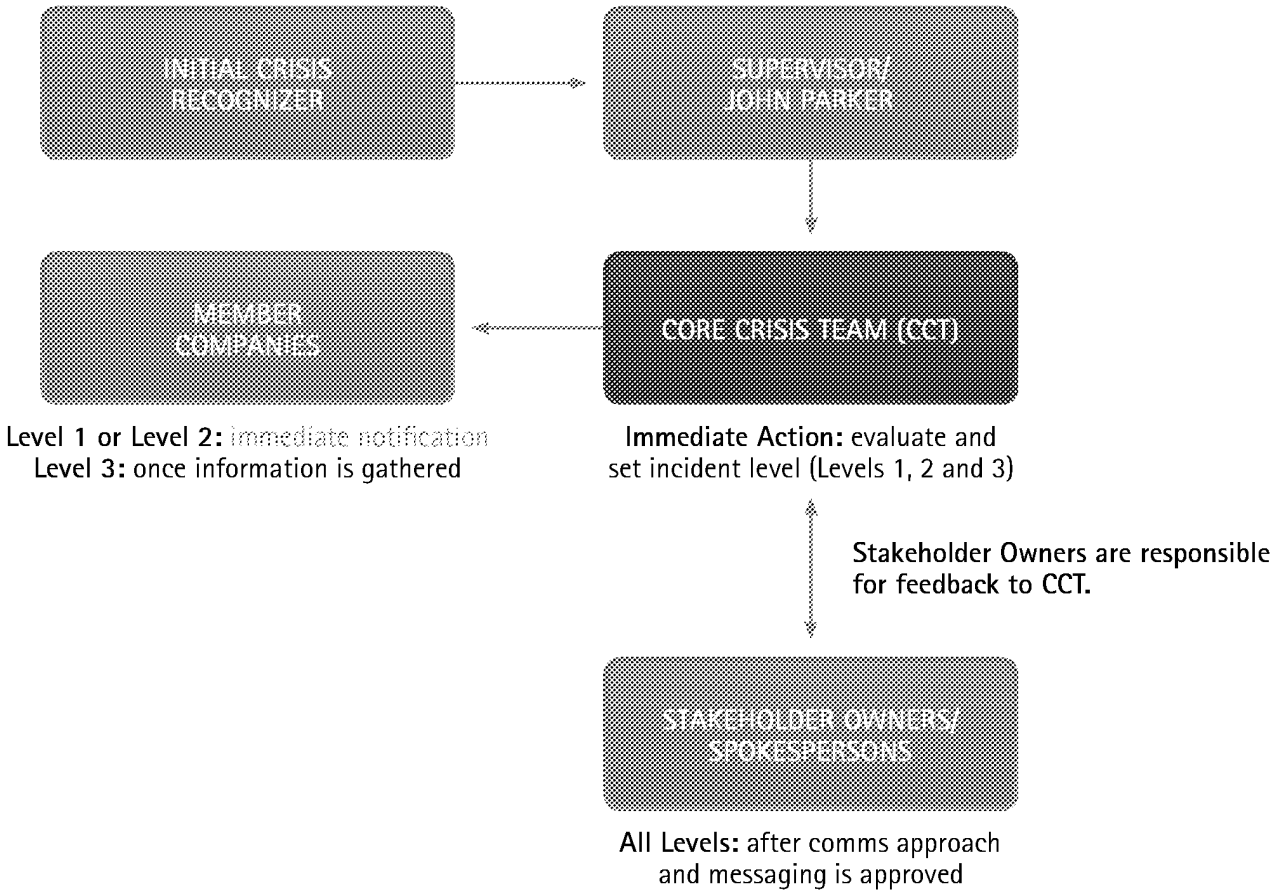
Categorization is to be determined by Core Crisis Team.

Key Questions for Determining Categorization

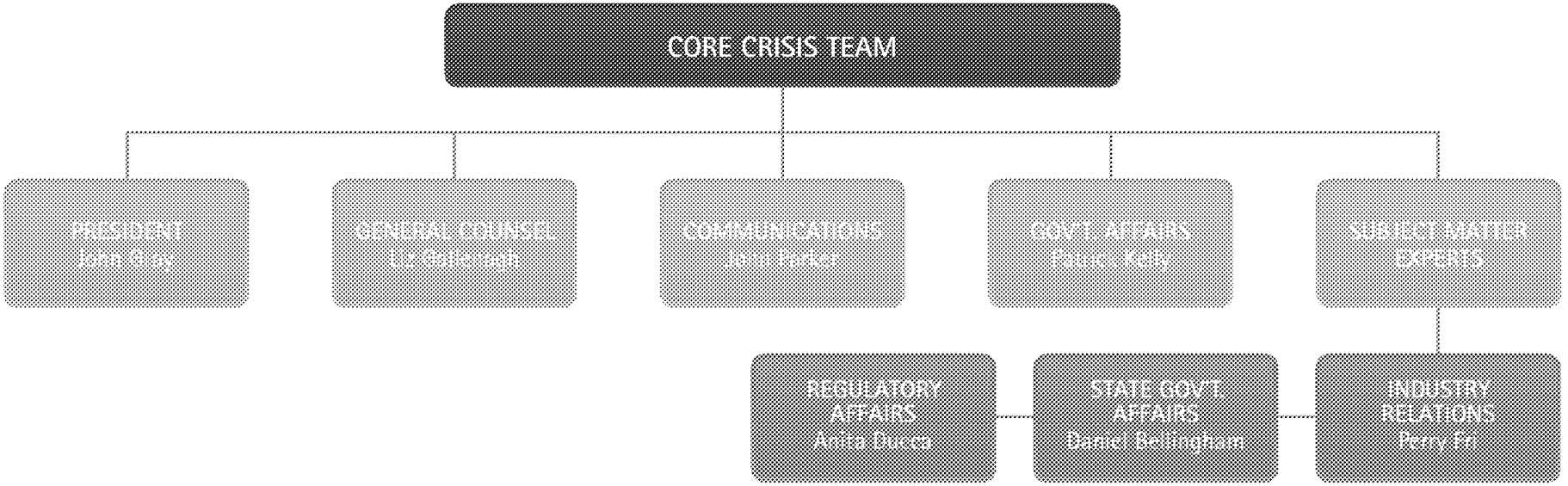
- What parts of the industry are impacted?
- What is the specific impact?
- How threatening is the potential impact?
- How quickly is the event expected to unfold?
- What is the potential for escalation?



Internal Notification



Who's In Charge?



Who Does What?

JOHN PARKER	Convener of Core Crisis Team
JOHN GRAY	Notify Executive Committee, Board of Directors
JOHN PARKER	Notify member company communications contacts
JOHN PARKER	Notify internal HDMA teams/relevant HDMA committees
JOHN PARKER	Establish monitoring process
JOHN PARKER AND ISSUE EXPERTS	Oversight of stakeholder/situational risk analysis
FULL CORE CRISIS TEAM	Determine communications approach
JOHN PARKER	Oversight of development of all communications materials

Who Approves?

APPROVAL ON DOCUMENTS

Input on documents:	Full CCT
Solicit input from Executive Committee:	John Gray or designee
First sign-off:	John Parker
Final sign-off:	John Gray

APPROVAL TO ACT

Input on action decisions:	Full CCT
Solicit input from Executive Committee:	John Gray or designee
Final sign-off:	John Gray

Who Talks To Whom?

Internal Stakeholders

STAKEHOLDER	STAKEHOLDER OWNER
Executive Committee	John Gray
HDMA Employees	John Gray
Government and Public Policy Council	Patrick Kelly
Industry Relations Council	Perry Fri
Public Affairs Council	John Parker
HDMA Member Committees	Committee leads
Member Company Employees	Member companies

External Stakeholders

STAKEHOLDER	STAKEHOLDER OWNER
Media/social media	John Parker
DEA	Anita Ducca
FDA	Anita Ducca
U.S. Congress	Patrick Kelly
ONDCP	Patrick Kelly
State Policymakers	Daniel Bellingham
Public Interest Advocates	HDMA member company contacts
Pharmacy Groups	HDMA member company contacts
Providers	HDMA member company contacts
Manufacturers	HDMA member company contacts
Investors and analysts	Individual member company IR contacts

Scenario Planning

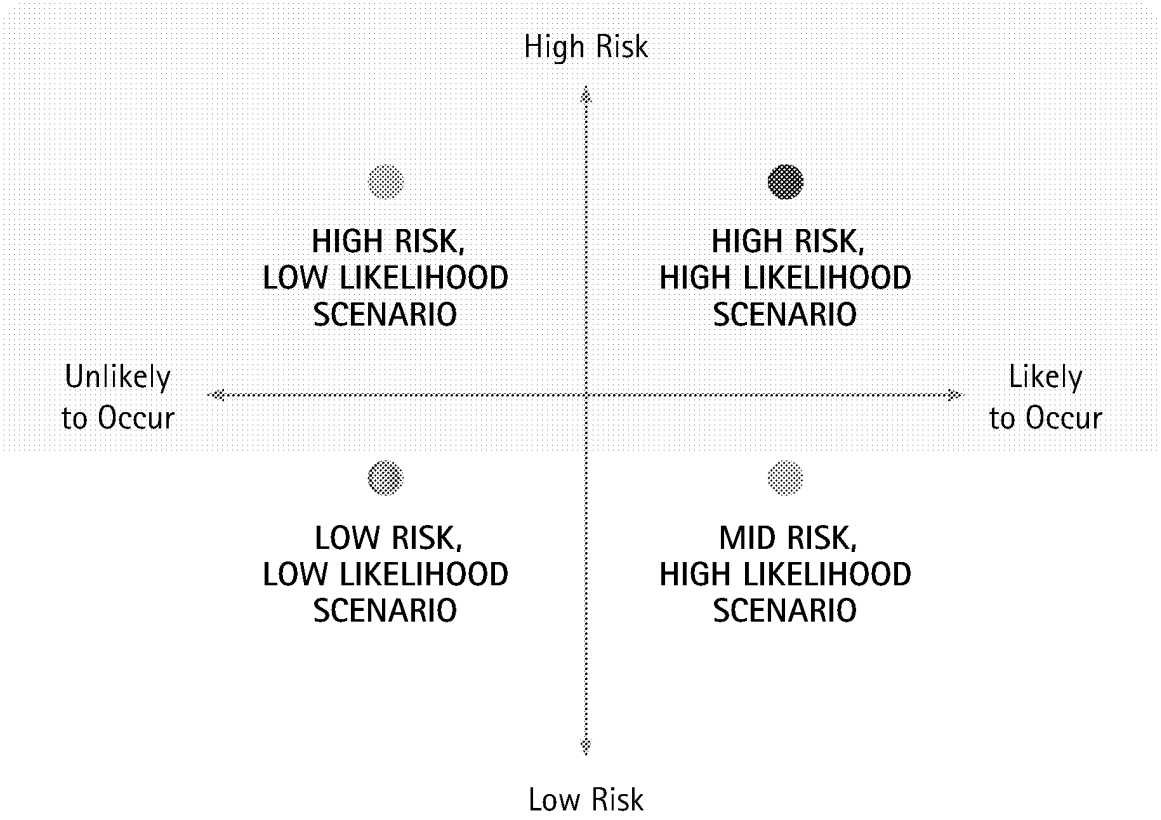
Mapping Out Scenarios

- Identify all potential scenarios for the given situation.
- Determine the relative likelihood and risk for each scenario.
- Map out all scenarios using the Risk Matrix (right) to identify highest likelihood/highest risk scenarios, which should be the focus of planning.

Key Questions

- What are the various developments that could happen next?
- How likely are those developments? What may alter the likelihood?
- What is the potential impact of the scenario? How damaging is the potential impact?

Risk Matrix



Communications Approach

APPROACH	DEFINITION	CONSIDERATIONS
Proactive/preemptive	Be the first party to announce the situation through a high visibility vehicle, such as a press release. Promptly communicate directly with key stakeholders.	• If you do not announce, how and when will the situation become public? • If you announce first, to what extent will you be able to drive the narrative? • What are the benefits and risks of being the first out with your message and controlling the timing of the announcement?
Responsive	After another party has announced the situation, respond to incoming stakeholder inquiries using pre-approved messaging.	• What will be the perception of the announcement coming from another party? How will your key stakeholders respond to this? • Is there a chance the situation will not become known if you do not announce? • How large and widespread will the announcement be if you are not part of it? • What are the benefits and risks of having another party first out with their message and controlling the timing of the announcement?
Hybrid	Proactively announce the situation to select key stakeholders without making a widespread, high visibility announcement.	• If only select stakeholders are communicated to, how likely is it that the information will become known to a larger audience anyway? Will you then have the opportunity to get your message across to the larger audience? • What will be the perception of being selective in making the announcement?

Communications Approach Options

For each scenario identified on the scenario risk matrix, identify the available communications approach options.

Use this chart as a worksheet to map out your plan.

Stakeholder Risk Analysis & Action Plan

PAGE 1 | PAGE 2

- Using the Stakeholder Risk Analysis and Action Plan Chart, identify the potential risks and opportunities associated with key stakeholders. This process will ensure that communications take into consideration all elements of the situation.
  - APCO and HDMA have already used this chart to conduct stakeholder risk analysis around the controlled substance diversion issue.
- The stakeholders to be evaluated may vary depending on the situation. Suggested stakeholders to consider are listed on the chart.
- For each stakeholder, fill out the following information on the chart:

Overview of Risk
Briefly list out known and potential risks associated with this stakeholder in the context of the crisis situation.

Overview of Opportunity
Briefly list out known and potential opportunities associated with this stakeholder in the context of the crisis situation.

Key Players
List out the most important and influential individuals/ groups associated with this stakeholder group.

Communications Approach
Based on the identified risks and opportunities, determine the best strategy and correlating tactics for communicating with the stakeholder.

Score
Based on the identified risks and opportunities, select an overall score for the stakeholder of low risk, medium risk, or high risk score.

Stakeholder Risk Analysis & Action Plan

PAGE 1 | PAGE 2

STAKEHOLDER	OVERVIEW OF RISK	OVERVIEW OF OPPORTUNITY	KEY PLAYERS	COMMUNICATIONS APPROACH	SCORE
Media/social media					LOW / MEDIUM / HIGH
U.S. Congress					LOW / MEDIUM / HIGH
State policymakers					LOW / MEDIUM / HIGH
DEA					LOW / MEDIUM / HIGH
FDA					LOW / MEDIUM / HIGH
ONDCP					LOW / MEDIUM / HIGH
Customers					LOW / MEDIUM / HIGH
Health care professionals					LOW / MEDIUM / HIGH
Employees					LOW / MEDIUM / HIGH
Public interest advocates					LOW / MEDIUM / HIGH
Financial community					LOW / MEDIUM / HIGH

Stakeholder Considerations

This chart helps HDMA to plan how it will communicate with key stakeholders, and it provides a process and clear team roles for this communication.

STAKEHOLDER	TIMING (1ST, 2ND, 3RD PRIORITY)	FORMAT (PHONE, EMAIL, IN PERSON)	MESSAGING FOCUS	OWNER
Media/social media				
U.S. Congress				
State policymakers				
DEA				
FDA				
ONDCP				
Customers				
Health care professionals				
Public interest advocates				
Employees				
Financial community				

Core Messaging

Draft core messages specific to the situation.

Objective: Develop and approve key language that will guide all communications materials and ensure consistency in messaging.

GUIDELINES:

- Draft "topline" messages, consisting of 3 to 5 message points that give an overview of the full narrative and that will likely be included in all communications materials.
- Determine the topic areas for which more detailed messages are needed, then draft the messages that fall under those topic areas.
- Every message point included in core messaging should be impactful and add value. Avoid unnecessary repetition and off-topic messages.
- Messages should be detailed enough to convey the right level of information, while being simple enough to be clearly understood by all audiences.

DRAFT CORE MESSAGES FOR HIGH RISK SCENARIOS:

- DEA Registration Suspension
- Diversion Lawsuit
- Criminal Indictment of Employee
- Congressional Inquiry
- Major Theft
- Counterfeit in Supply Chain
- Major Drug Shortage with Blame Placed on Industry
- Rescheduling
- Natural Disaster Emergency Response

If necessary, draft sub-messages tailored to key audiences.

These sub-messages should be consistent with the core messages, but may cover an additional topic area that is only of concern for that particular stakeholder.

Communication Materials

Draft all communication materials based on key messages.

CORE DOCUMENTS MAY INCLUDE:

- Press release and/or holding statement
- Q&A
- Internal communication (email/voicemail script)
- Investor relations script
- Fact sheet
- E-mails for other relevant/appropriate key audiences (key opinion leaders, government officials, patients, health care professionals)
- Social media/online messaging

Spokesperson Designation

Determine the best spokesperson(s) for the situation.
Immediately conduct messaging training or refresher for designated spokesperson(s).

DETERMINE BEST SPOKESPERSON(S) FOR THE SITUATION:

- Executive (John Gray)
- Communications (John Parker)
- Legal (Liz Gallenagh)
- Member company spokesperson

KEY QUESTIONS FOR DETERMINING BEST SPOKESPERSON(S):

- What function does the issue fall under?
- Who is best equipped to speak to the specifics of the situation? Who is best equipped to give a general overview of the situation?
- What are the risks and benefits of offering the spokesperson?
- Who puts the best "face" on the issue?
- Who is best able to articulate the industry's core values in the face of the crisis?
- Who has availability for training, media interviews, discussions with external and internal audiences?
- How is the spokesperson going to be used? Live interviews? Just as a name on a press release?

Third-Party Outreach

Identification

Identify potential third parties who could speak knowledgably about the issue by noting individuals or groups who have commented on the issue in news coverage, at conferences, or in published materials. Engage with subject matter experts at HDMA and member companies for additional insight into relevant third parties.

Engagement and Onboarding

- Reach out to gauge the level of interest and willingness to be contacted by media or speak to other stakeholders regarding the issue.
- Brief interested third parties on the issue, as appropriate.

Action

If use of third parties is determined to be appropriate for the situation and in support of the industry's communication goals:

- Refer media to third parties for comment.
- Ask third parties to engage with other stakeholders via email, letter, or other communication.

Potential Third Parties

- Academics
- Policy groups
- Customers
- Patient advocacy groups
- Legislators
- Regulators

Monitoring

Media and Social Media Monitoring

Immediately initiate real-time monitoring and determine monitoring protocol:

- Keywords to include in search
- Timing of monitoring reports (for example, as articles are published, once an hour, daily)
- Distribution list

Stakeholder Reaction Monitoring

Track key stakeholder reactions, including:

- Comments made via phone call or e-mail feedback
- Comments made publicly via quotes in news coverage or press releases
- Comments made on social media platforms

Note significant reactions (either positive or negative)

Message and/or Strategy Adjustment

Adjust messaging and/or strategy, if needed, based on media coverage and stakeholder reactions.

Capturing Lessons Learned

Generating a Crisis Report

Within one week after the crisis has concluded, communications team should generate a short report for the CCT that includes:

- Short description of the issue and how it developed
- Overview of the response
- List of actions/decisions that achieved the intended result
- List of actions/decisions that did not achieve the intended result
- Recommendations on dealing with future events

John Parker to lead meeting capturing lessons learned and process improvements to consider.

Core Crisis Team

CCT Meetings

In non-crisis times, CCT will meet regularly to:

- Report on potential issues on the horizon and discuss high risks
- Report from each functional area on potential threats (internal and external)
- Conduct postmortems on recent issues/crises to refine processes
- Review processes to ensure preparedness

Issue Monitoring Through Members

- At regular meetings, John Gray will solicit input from Executive Committee about potential emerging issues and concerns.
- Member companies, councils and committees will report in about potential issues and concerns.
- Member company communications, legal and public affairs teams should be made aware of the protocol to report issues into HDMA.

Diversion Issues

The following are scenarios that HDMA and the distribution industry could potentially face related to prescription drug diversion. Each scenario includes draft messaging, a draft media statement and other communications materials and considerations for HDMA and its members to use in response. While each hypothetical situation includes specific details, the materials should be tailored based on the specifics of the real scenario. The materials are designed to help HDMA and its members prepare for and quickly respond to industry-specific issues, queries and potential crises.

DIVERSION ISSUES SCENARIOS:

Scenario 1: DEA Registration Suspension

PAGE 1 | PAGE 2 | PAGE 3

The DEA has announced that it is suspending the controlled substance registration of an HDMA member at its distribution center. The DEA announced that the action was taken after its investigations found information that they believe suggests the distributor was fulfilling unusually large orders of controlled substances to three pharmacies. The pharmacies also had their licenses suspended for filling prescriptions the agency believes are "questionable." The HDMA member responded with a statement defending its corporate practices. HDMA has been fielding calls from media to comment on the industry's stance in fighting diversion.

Key Players

- HDMA members
- State policymakers (AG Office, state legislators, State Board of Pharmacy)
- U.S. Congress (Relevant location MOCs) and relevant committees
- DEA
- Media
- Customers
- Financial community

Key Considerations/Questions

- Who are the primary contacts at the member company that should be consulted on response?
- What are the member's expectations and recommendations regarding industry response?
- Does this present an opportunity for HDMA to proactively push its message of misdirected DEA enforcement with national media?
- Should HDMA or the member company proactively inform relevant members of Congress about the action to head off greater criticism?
- Are there policymakers or advocacy groups that HDMA should proactively engage to tell our side of the story and reassure that the industry is fulfilling their obligations in a responsible manner?
- Is there a concern or potential for this to become a bigger story about difficulty for legitimate patients to get their medications?
- Does HDMA have close relationships with the state board of pharmacy, state legislators or federal representatives that could provide support or balance the commentary?
- What are the facts surrounding the distribution to the pharmacies in this suit? Is there any concern about the member having failed to report?

Draft Materials

STATEMENT

- Our industry is committed to working collaboratively to address the serious national epidemic of prescription drug abuse and to being part of the solution. Although distributors do not license pharmacies, dispense drugs directly to patients or have access to individual patient information, we share a common goal with doctors, pharmacists, manufacturers, law enforcement and policymakers to ensure a safe and sufficient supply of medicines for patients in need, while keeping prescription drugs out of the hands of individuals who will abuse them.

Scenario 1: DEA Registration Suspension

PAGE 1 | PAGE 2 | PAGE 3

Primary pharmaceutical distributors support 'suspicious orders' monitoring and reporting to the DEA. Our members work proactively with DEA, local law enforcement and others to investigate potential cases of diversion. Primary distributors exercise due diligence and have processes in place to monitor and report suspicious orders and help ensure that those who purchase controlled substances from distributors intend to dispense them only to patients who need them.

TOUGH Q&A

What is HDMA's perspective on the registration suspension? Was this action warranted?

HDMA is not familiar with the particulars of this situation, but we are disappointed that the DEA appears to be pursuing a path of conflict, rather than collaboration, with our industry. Our members are committed to working to address the serious national epidemic of prescription drug abuse and to being part of the solution. Our industry shares a common commitment with the DEA to work toward a safe and efficient pharmaceutical supply chain for patients in need, as well as one that ensures controlled substances are only dispensed to the patients who need them.

Prescription drugs are different from illegal drugs and a different mindset is required from DEA and all stakeholders. Collaboration and transparency are critical to preventing diversion and we believe that this type of enforcement is unproductive in solving this complex challenge.

Now that the DEA has taken this action at several facilities, should the public be concerned that beyond the actions of one company, the industry as a whole is not taking appropriate steps to help prevent diversion?

Our members follow rigorous statutory and regulatory requirements to detect and prevent diversion. Every distributor must monitor suspicious orders and report to the DEA if it appears a pharmacy's controlled substances volume or pattern of ordering might signal diversion. All orders of controlled substances must be reported to the DEA's reporting system, ARCOS, which tracks the movement of controlled substances from the manufacturer through distribution to the healthcare provider or retailer responsible for furnishing or admistering the product.

Additionally, HDMA has developed Industry Compliance Guidelines (ICGs) for diversion prevention and the reporting of suspicious orders as part of our industry's ongoing commitment to the safe and efficient distribution of all prescription medicines. These ICGs are consistent with, and further extend, the distributors' track record of supporting and implementing initiatives designed to improve the safety, security and integrity of the medicine supply.

The public should feel confident that the nation's primary distribution industry is committed to working collaboratively to help address the serious national epidemic of prescription drug abuse and to being part of the solution. Although distributors do not dispense drugs directly to patients and do not have access to individual patient information, we share a common goal with doctors, pharmacists, manufacturers, law enforcement and policymakers to help ensure a safe and sufficient supply of medicines for patients in need, while keeping prescription drugs out of the hands of individuals who will abuse them.

Scenario 1: DEA Registration Suspension

PAGE 1 | PAGE 2 | PAGE 3

Could this impact patients' ability to access prescription drugs that they legitimately need?

At this time, we cannot predict the impact that this action could have on the local community. We understand that it is important to carefully balance combatting diversion while at the same time not limiting access to appropriately prescribed medicines for patients or potentially putting legitimate pharmacies out of business. In light of these concerns, HDMA has encouraged DEA to provide greater information sharing and more clarity around distributors' responsibilities for controlled substance monitoring and reporting.

Doesn't the industry have a profit motive to ignore signs of diversion?

No. It is in our members' best interest to ensure the supply chain is secure. Our industry is committed to doing whatever it can to protect patient safety and access to medicines through the safe and efficient distribution of healthcare products and services. Primary distributors help pharmacies, hospitals, nursing homes, clinics and other health providers keep their shelves stocked with the prescription and OTC medicines and health products that patients need every day.

Scenario 2: Diversion Lawsuit

PAGE 1 | PAGE 2

A state attorney general has filed a lawsuit against several healthcare distributors claiming they failed to adequately monitor for diversion of prescription drugs in the state to "pill mill" pain clinics. Four HDMA members are named as defendants. The attorney general held a press conference and issued a release announcing the suit. In addition, several members of Congress issued statements indicating that they will be investigating the role of the distribution industry in diversion. *The New York Times* has called HDMA for comment on the suit and insight into what the industry does to combat diversion.

Key Players

- HDMA members
- State policymakers (AG Office, state legislators, State Board of Pharmacy)
- U.S. Congress
- DEA
- Media
- Customers
- Financial community

Key Considerations/Questions

- Which distributors are named as defendants and who are the primary contacts with the impacted member companies that should be consulted on response?
- Does HDMA have close relationships with the state board of pharmacy, state legislators or representatives that could provide more balance to the discussion?
- Are there policymakers or advocacy groups that HDMA should proactively engage to tell our side of the story and reassure that the industry is responsible?
- What are the facts surrounding the distribution to the alleged "pill mills" in the suit? Is there any concern about a member having failed to report?
- How does each of the impacted member companies plan to respond? What are their expectations of HDMA?

Draft Materials

STATEMENT

As an industry we are committed to working collaboratively to address the serious national epidemic of prescription drug abuse and to being part of the solution. Although distributors do not dispense drugs directly to patients and do not have access to individual patient information, we share a common goal with doctors, pharmacists, manufacturers, law enforcement and policymakers to ensure a safe and sufficient supply of medicines for patients in need, while keeping prescription drugs out of the hands of individuals who will abuse them.

Primary healthcare distributors support suspicious orders monitoring and reporting to the DEA as an important component of addressing diversion of controlled substances. Our members work proactively with DEA, local law enforcement and others to investigate potential cases of diversion. Our members exercise due diligence and have processes in place to monitor and report suspicious orders to help ensure that those who purchase controlled substances from distributors intend to dispense them only to patients who need them.

Scenario 2: Diversion Lawsuit

PAGE 1 | PAGE 2

TOUGH Q&A

The lawsuit claims these distributors were shipping what appeared to be exorbitant amounts of prescription pain killers to these clinics. Shouldn't they have noticed that this was unusually high amount and called attention to it with the DEA?

HDMA is not familiar with the specific claims made in the lawsuit. We can tell you that our members are registered with the DEA and follow rigorous statutory and regulatory requirements to detect and prevent diversion. Every distributor must monitor suspicious orders and report to the DEA if it appears a pharmacy's controlled substances volume or pattern of ordering might signal diversion. All orders of controlled substances must be reported to the DEA's reporting system, ARCOS, which tracks controlled substances from the manufacturer through distribution to the dispensing/retail level.

Our members do not dispense drugs directly to patients, do not have access to individual patient information and do not license pharmacies or healthcare providers that dispense these drugs. Despite this, in some cases they are being held accountable, with incomplete information, for diversion from parts of the supply chain they do not control.

Because only the DEA has access to aggregated ARCOS data, distributors do not have the independent ability to determine whether a pharmacy is ordering from multiple distributors. In addition, there are a variety of factors that could influence the volume of orders for controlled substances, including the pharmacy size, patient demographics, and proximity to a hospital or major healthcare provider. In light of these information limitations, distributors have developed complex monitoring systems and follow best practices in their efforts to detect and prevent diversion.

Isn't it true that these large, publically traded companies are making millions of dollars from the diversion of prescription drugs? Shouldn't patient safety be put before profits?

Patient safety is put before profits. Our industry is committed to doing whatever it can to protect patient safety and access to medicines through the safe and efficient distribution of healthcare products and services. Primary distributors help pharmacies, hospitals, nursing homes, clinics and other health providers keep their shelves stocked with the prescription and OTC medicines and health products that patients need every day. It is in our members' best interest to ensure the supply chain is secure.

If the DEA is not providing aggregated data why don't your members share more information with each other so they can better spot large orders and potential diversion?

Our industry has asked the DEA to provide blinded and aggregated data from ARCOS that could be further used to assess product orders. Anti-trust laws make it impractical for data sharing among industry companies. However, our members' diversion investigation teams often collaborate with each other, together with DEA and local law enforcement, to investigate potential cases of diversion.

In addition, many of our members participate in and provide financial support to the National Association of Drug Diversion Investigators, which is a non-profit that facilitates cooperation between the public and private sector in the prevention and investigation of diversion.

Scenario 3: Criminal Indictment of Employee

PAGE 1 | PAGE 2

A U.S. attorney, the DEA and local law enforcement agencies announced indictments against 10 individuals involved in an alleged prescription drug distribution ring. One of the indicted individuals was an employee at an HDMA member facility. The employee allegedly falsified documents provided to the DEA about deliveries of controlled substances to pain clinics involved in the ring. The employee was paid in exchange for under-reporting the amount of controlled substances being ordered by the pain clinics. The member is concerned that it may be brought into the criminal suit, despite the fact that the employee acted alone and was immediately terminated following notification of the indictment. A regional daily newspaper reported on the initial indictment and is following up with a deeper story about the diversion of prescription drugs and the supply chain. The reporter reached out to HDMA for comment.

Key Players

- HDMA members
- State policymakers (local law enforcement, state legislators, state Board of Pharmacy)
- U.S. Congress
- DEA
- Media
- Customers

Key Considerations/Questions

- Did the member follow HDMA guidelines and the legal requirements for reporting?
- How long was the employee with the company and how long did the behavior go on?
- Given concerns about liability for the member, what are their expectations for HDMA's communications? Do they have recommendations for HDMA's response?
- Are there other member companies that may be vulnerable to similar employee schemes?
- Could this issue draw into question the integrity of the data reported to ARCOS?
- Does HDMA have allies that could speak to the industry best practices with media?

Draft Materials

STATEMENT

HDMA is not aware of the specifics of this case, but we understand that the employee acted alone and made a deliberate effort to conceal his actions from [company], which is actively cooperating with the ongoing investigation.

As an industry, we are committed to working collaboratively to address the serious national epidemic of prescription drug abuse and to being part of the solution. All primary distributors follow rigorous statutory and regulatory requirements to detect and prevent diversion. Primary distributors exercise due diligence and have processes in place to monitor and report suspicious orders to help ensure that those who purchase controlled substances from distributors intend to dispense them only to patients who need them. Every distributor must monitor suspicious orders and report to the DEA if it appears a pharmacy's controlled substances volume or pattern of

Scenario 3: Criminal Indictment of Employee

PAGE 1 | PAGE 2

ordering might signal diversion. All orders of controlled substances must be reported to the DEA's reporting system, ARCOS, which tracks controlled substances from the manufacturer through distribution to the dispensing/retail level.

TOUGH Q&A

What does the industry do to screen and monitor its employees?

Each of our members has its own policies and procedures in place to screen and monitor employees, including those who work directly with processing orders for controlled substances. As an industry, we are committed to addressing the serious national epidemic of prescription drug abuse and our members employ best practices and rigorous systems to maintain a safe and efficient drug supply.

Is the industry taking additional actions in light of this event?

While the U.S. is fortunate to have one of the safest and strongest pharmaceutical supply chains in the world, as an industry we are continuously evaluating our processes and procedures.

How do distributors track and report controlled substances orders? Isn't this information collection automated? How could this employee change the numbers?

Our members follow rigorous statutory and regulatory requirements to detect and prevent diversion. Every distributor must monitor suspicious orders and report to the DEA if it appears a pharmacy's controlled substances volume or pattern of ordering might signal diversion. All orders of controlled substances must be regularly submitted to the DEA's reporting system, ARCOS, which tracks controlled substances from the manufacturer through distribution to the dispensing/retail level. Each member is responsible for developing the systems to comply with these requirements.

Should the industry have more standardized reporting processes and guidelines?

The distribution industry is highly regulated and our members follow rigorous statutory and regulatory requirements to detect and prevent diversion. Because of anti-trust concerns, individual distributors must make their own decisions regarding their business practices and their processes to comply with the legal requirements.

HDMA has developed Industry Compliance Guidelines (ICGs) for diversion prevention and the reporting of suspicious orders as part of our industry's ongoing commitment to the safe and efficient distribution of all prescription medicines. These ICGs are consistent with, and further extend, the distributors' track record of supporting and implementing initiatives designed to improve the safety, security and integrity of the medicine supply.

Scenario 4: Congressional Inquiry

PAGE 1 | PAGE 2

One of the Congressional health committees has announced that it will be taking a closer look at the prescription drug diversion and abuse problem in the U.S. and the various corporate players involved in the issue. Several HDMA members have received formal letters from the committee seeking information and documentation about their internal anti-diversion programs with a deadline of one month to reply. In addition, HDMA has been contacted by committee staff seeking further information from the industry about what it does to prevent diversion in the supply chain. The probe has been reported by inside-the-Beltway publications. One senior member of Congress has made several critical comments about the industry, implying that it is focused on profits at the expense of American lives. It's anticipated that the inquiry will result in a committee hearing on the issue at a later point.

Key Players

- HDMA members
- U.S. Congress (especially relevant committee members)
- ONDCP
- DEA
- FDA
- Media
- Customers
- Manufacturers
- Financial Community

Key Considerations/Questions

- What member companies have received requests for information and documentation?
- Who at the member companies should be consulted on response?
- Have pharmacies or manufacturers been included in the inquiry, or is it looking solely at the distribution industry?
- What are specific questions from the probe and is the industry able to answer all questions? Is there information that is missing or needs to be compiled?
- What are the member's expectations and recommendations regarding industry response?
- Is there a concern or potential for this to become a bigger story among member's investors and analyst communities? Does this action need to be reported by the companies to the SEC?

Draft Materials

STATEMENT

Our industry is committed to working collaboratively to address the serious national epidemic of prescription drug abuse and to being part of the solution. We are working with Congress and the committee staff to provide the information they have requested and offer insight into the distribution industry's role in combatting prescription drug diversion. We share a common commitment with policymakers, law enforcement, and the broader health care community to ensure that we have a safe and efficient pharmaceutical supply chain for patients in need and that controlled substances are only dispensed to the patients who need them.

Scenario 4: Congressional Inquiry

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Primary pharmaceutical distributors support 'suspicious orders' monitoring and reporting to the DEA as an important component of addressing diversion of controlled substances. Our members work proactively with DEA, local law enforcement and others to investigate potential cases of diversion. Primary distributors exercise due diligence and have processes in place to monitor and report suspicious orders to help ensure that those who purchase controlled substances from distributors intend to dispense them only to patients who need them.

TOUGH Q&A

What does the industry do to prevent diversion? Couldn't it be doing more?

Our members follow rigorous statutory and regulatory requirements to detect and prevent diversion. Every distributor must monitor suspicious orders and report to the DEA if it appears a pharmacy's controlled substances volume or pattern of ordering might signal diversion. All orders of controlled substances must be reported to the DEA's reporting system, ARCOS, which tracks controlled substances from the manufacturer through distribution to the dispensing/retail level.

HDMA has developed Industry Compliance Guidelines (ICGs) for diversion prevention and the reporting of suspicious orders as part of our industry's ongoing commitment to the safe and efficient distribution of all prescription medicines. These ICGs are consistent with, and further extend, the distributors' track record of supporting and implementing initiatives designed to improve the safety, security and integrity of the medicine supply.

Doesn't the industry have a profit motive to ignore signs of diversion?

Our industry is committed to doing whatever it can to protect patient safety and access to medicines through the safe and efficient distribution of healthcare products and services. Primary distributors help pharmacies, hospitals, nursing homes, clinics and other health providers keep their shelves stocked with the prescription and OTC medicines and health products that patients need every day. It is in our members' best interest to ensure the supply chain is secure.

Should the public be concerned that the industry as a whole is not being responsible or taking enough steps to prevent diversion?

The public should feel confident that the nation's primary distribution industry is committed to working collaboratively to address the serious national epidemic of prescription drug abuse and to being part of the solution. Although distributors do not dispense drugs directly to patients and do not have access to individual patient information, we share a common goal with doctors, pharmacists, manufacturers, law enforcement and policymakers to ensure a safe and sufficient supply of medicines for patients in need, while keeping prescription drugs out of the hands of individuals who will abuse them.

Primary distributors exercise due diligence and have processes in place to monitor and report suspicious orders to help ensure that those who purchase controlled substances from distributors intend to dispense them to patients who need them.

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Scenario 5: Major Theft

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An HDMA member company's delivery truck was ambushed shortly after leaving its distribution facility to make early morning deliveries to pharmacies. The truck driver was shot and killed, and the armed robbers stole several bins filled with controlled substances. The criminals remain at large, with the local police department and DEA actively investigating the crime. The incident has been widely reported across local news outlets. A local representative released a statement that his office will do everything in its power to assist in the investigation and ensure that distribution facilities are "providing appropriate security measures" to keep employees and the community safe. Beyond sharing a short statement of condolence to the family of the deceased, the HDMA member company has not been forthcoming with information on the incident, citing the ongoing law enforcement investigation. This response has drawn criticism in the media that the company is at fault for not doing enough to protect its employees. Other members are concerned about the impact of the negative publicity on the industry as a whole.

Key Players

- HDMA lembers
- State policymakers (local law enforcement, state legislators)
- U.S. Congress
- DEA
- Media
- Employees
- Public interest advocates
- Customers
- Manufacturers
- ONDCP

Key Considerations/Questions

- What safety policies were in place to protect the employee in this case?
- How is the member company interacting with the family of the victim? Is the family speaking publically about the deceased and the case?
- Will the incident impact other industry employees – at this company or others?
- Can the stolen drugs be traced?
- Are there potential implications with labor unions to be considered?

Draft Materials

STATEMENT

Our industry is saddened by this tragedy and we send our heartfelt condolences to the family and friends of Mr. [name]. This tragedy is a stark reminder of the scope of the nation's prescription drug abuse epidemic and the challenge of combatting the increasingly sophisticated criminal groups that attempt to breach the security of the legitimate supply chain. As a country, we must come together to combat prescription drug abuse at every step in the chain – from patients and prescription drug abusers, to doctors, to pharmacists to distributors and manufacturers – and the distribution industry is committed to playing its part.

Scenario 5: Major Theft

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We remain dedicated to addressing this serious national epidemic and will continue to work with law enforcement, regulators, and supply chain partners to combat theft and diversion and ensure the integrity of the healthcare supply chain. HDMA has been a longtime supporter of laws to improve the ability to track diverted pharmaceutical products and we support laws that increase resources for law enforcement and increase penalties for criminals that steal and introduce diverted products into the healthcare system.

TOUGH Q&A

What does the industry do to protect employees from this type of violence?

Our members have robust and sophisticated security systems and procedures to protect the safety of employees and ensure the nation's medicine supplies are stored and transported in a secure environment.

HDMA has been a longtime supporter of laws to improve the ability to trace diverted pharmaceutical products and we support laws that increase penalties for criminals that steal and introduce diverted products into the healthcare system.

With this incident and robberies of pharmacies being reported around the country, should the public and industry employees be concerned with the escalating violence surrounding prescription drug diversion?

This type of brazen and senseless violence is only further indication that as a country, we must come together to combat prescription drug abuse at every step in the healthcare supply chain – from patients and prescription drug abusers, to doctors, to pharmacists to distributors and manufacturers.

Does the industry have the capability to track these drugs to find the criminals responsible?

At this time, there is limited ability to trace these controlled substances. Following a theft the pills are typically removed from their original packaging bins; because of this we have limited ability to track a pill back to the original case or lot. HDMA has been a leader in working collaboratively with manufacturers, pharmacies and others in the supply chain to a national solution to enhance traceability in the supply chain. HDMA supports the passage of a uniform federal traceability framework that would enhance the safety and security of the supply chain to the benefit of all.

Scenario 6: Rescheduling

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In the wake of the nation's growing prescription drug abuse epidemic, a bill has quickly moved through both the House and the Senate requiring hydrocodone to be classified as schedule II, but containing no allowances for handling procedures other than those used for other class II controlled substances. Distributors are given six months to comply with handling procedures. Calls are flooding in from members wanting to know what HDMA is doing to advocate for their interests.

Key Players

- U.S. senators and representatives supporting the legislation
- Professional organizations, such as those representing pharmacists, pharmacies and healthcare providers FDA
- DEA
- HDMA members
- Media

Key Considerations/Questions

- What is the plan for outreach with the DEA?
- Who is responsible for regulation/implementation?
- To what extent are carve-outs/amendments to the legislation still feasible?
- What efforts did HDMA take to represent the industry's interests on the legislation while it was moving through Congress?
- How much time/extension would we need?
- What is critical for compliance?

Draft Materials

STATEMENT

While we do not manufacture, dispense or prescribe hydrocodone combination products, our industry will be profoundly affected by the recent decision to reschedule these products.

The processes in place to secure existing schedule II controlled substances within distribution facilities differ significantly from those currently in place to secure hydrocodone combination products. As a result, this legislation creates a multitude of unforeseen logistical complications and unintended consequences for the distribution industry, including the following:

1. Hydrocodone combination products must go from being stored in a secure cage to a vault. All of the security features of these storage facilities are specifically and clearly defined by regulation. Because there are a very large number of hydrocodone products, this will mean a need for increased storage capacity within our members' vaults - an average of 1,200 additional square feet of storage capacity per warehouse, or roughly the size of a small to medium house.
2. DEA must review and approve all designs before construction and inspect and approve them after construction is complete. This must occur for a majority of our members' 150 warehouses, as well as for those of many more of the over 700 distributors currently registered with the DEA.
3. Construction takes time. Each warehouse will have to be individually assessed and vaults redesigned to accommodate space, workflow and other specifications.
4. There are currently very few design/construction firms with the capacity to build vaults to DEA specifications. Smaller distributors with more limited bargaining power may be significantly disadvantaged.

Scenario 6: Rescheduling

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5. Other controlled substances and hundreds of other products, within the cage and throughout the warehouse, will also have to be reorganized and moved to accommodate the expanded vault, disrupting workflow and hindering our members' efficient delivery of these lifesaving and life-enhancing products. Many products will have to be moved as many as three times — before, during and after construction.

We acknowledge the reality of our nation's prescription drug abuse problem and are committed to working collaboratively to address it with stakeholders across the supply chain. As we understand it, the rescheduling is intended to affect the availability to the end user of the product. However, requiring significant additional security and ordering requirements in an already secure environment will only add costs, hinder efficient processes and do little, if anything, to reduce diversion.

TOUGH Q&A

If you don't support the new legislation, what is the distribution industry willing to do to reduce the prescription drug abuse epidemic?

We acknowledge that there is a prescription drug abuse problem and are committed to working collaboratively to address it. However, we want to stress that requiring significant additional security and ordering requirements in an already secure environment will only add costs, hinder efficient processes and do little, if anything, to reduce diversion. We believe that all stakeholders must work together to produce meaningful results in combatting prescription drug abuse, and we are dedicated to being a part of that solution.

Aren't the costs to retrofit existing distribution warehouses a drop in the bucket for your multi-billion dollar industry?

We want to be clear that the costs of retrofitting extend beyond the simple dollars and cents dedicated to construction, and that it is not only our industry that will be affected by these requirements. Retrofitting involves working with specialized contractors to produce facilities that meet exacting specifications and must be thoroughly reviewed by the DEA twice during the course of construction, using already limited DEA resources. The costs of complying with the new regulatory regime also include the logistical complications of moving significant stock, much of which must also remain heavily secured, as many as three times throughout the construction efforts. This will contribute to loss of efficiency through modification of workflows in a majority of HDMA members' 150 warehouses that must be retrofitted. The effects of these efforts will be felt to some extent in the more than 200,000 pharmacies and other outlets that our members serve every day. Many of these pharmacies will also have to significantly modify their facilities in order to meet the new requirements for hydrocodone combination products storage.

Why are you against requiring more security for controlled substances that are being diverted for unlawful use?

Our industry is committed to working collaboratively to address the prescription drug abuse epidemic. However, the controlled substances being targeted are not being diverted through our facilities. The current security measures in place for hydrocodone combination products are extensive and effective at securing the supplies of these products within distribution centers. While the end goal of this legislation is admirable, the logistical impact of the regulations will have broad-reaching complications that do nothing to achieve that end goal.

Supply Chain Security Issues

The following are scenarios that HDMA and the distribution industry could potentially face related to the overall prescription drug supply chain. Each scenario includes draft messaging, a draft media statement and other communications materials and considerations for HDMA and its members to use in response. While each hypothetical situation includes specific details, the materials should be tailored based on the specifics of the real scenario. The materials are designed to help HDMA and its members prepare for and quickly respond to industry-specific issues, queries and potential crises.

SUPPLY CHAIN SECURITY ISSUES SCENARIOS:

- Scenario 1: Counterfeit in Supply Chain
- Scenario 2: Major Drug Shortage with Blame Placed on Industry
- Scenario 3: Natural Disaster Emergency Response

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Scenario 1: Counterfeit in Supply Chain

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Distributors are facing scrutiny after a counterfeit blood pressure medication was found in 15 pharmacies in three states. Two people have been hospitalized with dangerously high blood pressure after taking the counterfeit pills. Each of the 15 pharmacies contracts with at least two distributors, and it is unclear at what point in the supply chain the counterfeits entered, but each of the pharmacies implicated has a contract with at least one HDMA member. John Gray receives a call from a reporter at a local newspaper asking for the industry's perspective on the situation.

Key Players

- HDMA members
- U.S. Congress
- FDA
- Media
- Customers
- Secondary distributors
- Patients

Key Considerations/Questions

- How are members handling the situation? What measures are being taken to isolate the counterfeits and identify their entry point into the supply chain? What is their public position?
- To what extent will this affect other members?
- What players will be involved in the solution?
- Who is being blamed in the public discourse?
- Are any public officials involved? What is the potential legislative/regulatory backlash?

Draft Materials

STATEMENT

While the U.S. is fortunate to have one of the safest and strongest pharmaceutical supply chains in the world, incidents like this remind us of the vulnerability of the supply chain and the importance of constant vigilance to safeguard the products that promote the health and well-being of every American.

We wish to convey our sincere sympathy and support for those affected by the counterfeit medication, as well as their families and friends. The investigation remains underway and we await the FDA's findings. While incidents like this occur infrequently, any situation that puts patients at risk is a clear indication that we need a comprehensive, uniform and national supply chain framework to trace product movement in the supply chain. Delivering medical products safely and securely to the patients who need them is our industry's prime mission, and we will continue to do everything in our power to work with the entire pharmaceutical supply chain, policymakers and regulators to prevent future incidents.

Scenario 1: Counterfeit in Supply Chain

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TOUGH Q&A

How could this happen?

The FDA is investigating the circumstances of this incident and can speak to their findings. What we do know is that our industry has extensive safeguards in place to prevent distribution of counterfeit medications, and our members are continually monitoring these procedures. Our members' highest priority is ensuring the safety of the products they deliver, and this incident is being met with a renewed resolve to continuously enhance and build upon safety measures already in place.

What is the industry doing to make sure this never happens again?

First, we would like to stress that there is no evidence that the counterfeit entered the supply chain through one of our members. That said, in light of this incident our members are evaluating their security protocols to assure that they are doing everything in their power to safeguard the medicines they distribute. The best way to protect the supply chain is by instituting a uniform federal traceability solution to track products, which HDMA has advocated for consistently for a number of years.

Scenario 2: Major Drug Shortage with Blame Placed on Industry

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A nationally known health reporter writes an "exposé" about the distribution industry after receiving a call from a father in his hometown who claimed he was not able to find methotrexate for his son's leukemia even after visiting all five local pharmacies. The piece implicates the distribution industry for drug shortages, saying that these "supply chain manipulators" have a business interest in withholding supply in order to drive up prices. The piece also cites a nationwide 48 percent increase in wholesale prices for intramuscular methotrexate over the last 12 months, corresponding with decreases in availability, as proof that distributors are profiting off sick children with a life-threatening disease. HDMA was asked to comment on the story.

Key Players

- Customers
- U.S. Congress
- FDA
- Media
- HDMA members

Key Considerations/Questions

- How are members handling the situation? What measures are being taken to ensure any available supply of the product is getting to the people who need it at a reasonable price? What is their public strategy?
- To what extent will this affect other members?
- What players will be involved in the solution?
- How likely is this to become a big issue?
- What strategy can combat the negative claims without exacerbating the situation?
- Who is being blamed in the public discourse?
- Are any public officials involved? What is the potential legislative/regulatory backlash?

Draft Materials

STATEMENT

Primary healthcare distributors do not control the availability of prescription drug supplies from manufacturers. We are committed to protecting patient safety and access to medicines through the safe and efficient distribution of healthcare products and services. Fundamental to this commitment is confirming that we are doing everything in our power to get patients the medicines they need.

Unfortunately, multiple factors can lead to medication shortages, hindering our ability to provide access to lifesaving and life-enhancing pharmaceuticals. These factors include limited manufacturer production capacity, unforeseen demand spikes, and FDA actions affecting production, all of which can reduce the available supply of a product. This requires all of us to work together to ensure that patients have access to the treatment they need when they need it.

Scenario 2: Major Drug Shortage with Blame Placed on Industry

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TOUGH Q&A

What caused the shortage?

Multiple factors contribute to shortages, and the FDA is currently investigating the causes of this particular shortage. In the past, reduced supplies of raw materials, reduced manufacturer production capacity, and FDA-ordered plant shutdowns have caused shortages. Whatever the root cause, distributors are working to ensure supplies are available to the patients who need them as soon as possible.

I've heard that some distributors are stockpiling the scarce drug and selling it at higher prices— is that true?

HDMA's members are primary distributors and do not condone or participate in the gray market for prescription drugs, nor do they engage in ethically unsound practices such as stockpiling supplies or price manipulation. For the most part, primary distributors purchase a majority of product directly from the manufacturer of a drug and distribute a majority of these supplies directly to the customer. Our members are in the business of creating efficiencies and getting patients the treatment they need when they need it, not from manipulating the supply to artificially inflate prices.

Why should distributors have control over drug supplies, if they can't prevent life-threatening shortages?

Primary healthcare distributors do not control the availability of prescription drug supplies. What we do is bring efficiency to the healthcare distribution process by providing an array of services, including aggregate ordering and inventory management tracking, among others. These capabilities allow us to provide early warning to pharmacies, hospitals and other healthcare providers about potential shortages. In addition, without primary distributors, pharmacies, hospitals and other healthcare providers would have to coordinate deliveries and ordering from thousands of manufacturers – a huge logistical burden that would create significant instability in the supply chain and cost billions of dollars for the nation's healthcare system.

Scenario 3: Natural Disaster Emergency Response

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A major earthquake hits a coastal U.S. city, triggering a tsunami. In the aftershocks there is extensive damage to buildings and roads, and a critical bridge to the city sinks, cutting off a major interstate. Traffic across other bridges to the city is restricted for several days, pending extensive reviews of the bridges' structural integrity. Soft soils in some districts of the city lead to several major structural collapses, including three control towers at the local cargo airport. An estimated 40,000 people are forced to evacuate their homes and flights into and out of the major arrival point for air cargo are severely restricted. Red Cross, FEMA and National Guard are on the ground directing disaster response efforts. HDMA members have been coordinating with the relevant authorities since the disaster hit. As focus turns on disaster recovery, a national reporter is seeking comment from HDMA about efforts to keep medicines in supply for the region.

Key Players

- FEMA
- Red Cross
- National Guard
- State policymakers and local officials
- Media
- HDMA members
- US Congress

Key Considerations/Questions

- Are distribution warehouses damaged and/or have employees been hurt or killed?
- What members are most impacted and what are other HDMA members doing to help?
- Are there security concerns?
- Who at HDMA is coordinating response efforts with the member companies? What does this involve?
- What areas are most impacted? What about the patients who are most at risk?
- What agencies/groups is the industry coordinating with on the ground? FEMA? National Guard? Red Cross?

Draft Materials

STATEMENT

In the wake of the recent disaster, there is a critical need to maintain healthcare supplies, from chronic and maintenance medicines to trauma provisions. The nation's primary healthcare distributors are working with FEMA, the Red Cross and the National Guard on the ground in Seattle to ensure that the people hit by the earthquake and tsunami have access to the lifesaving pharmaceutical and healthcare products they need. Further, through the Rx Response coalition, healthcare distributors are working to identify areas of need and direct supplies to them as quickly as possible.

Our thoughts and prayers go out to the people of [city] and the surrounding area, and we mourn the devastation and loss of life. HDMA's members will continue to

Scenario 3: Natural Disaster Emergency Response

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be on the ground, supporting the response and recovery efforts, for as long as we're needed. As the region seeks to recover from this devastating event, we will continue to coordinate with emergency response personnel and ensure that the pharmacies serving shelters and displacement areas are able to provide medications to the people who need them.

TOUGH Q&A

How is the industry ensuring continuity of the medicine supply?

We are coordinating with emergency response personnel to identify areas of need and rapidly supplying them with critical healthcare products. Through the Rx Response coalition, we are identifying open pharmacies and directing critical supplies to those locations.

What has the industry done to prepare for this kind of disaster?

We participate in the Rx Response coalition, which develops rapid response protocols for disasters. In addition, our members plan for emergency response scenarios by maintaining strategic supplies of emergency-critical medicines and frequently reviewing disaster response protocols.

Is there a concern that patients will not be able to get their medicines?

The needs of patients with both chronic and acute medical conditions are often a particular concern in the aftermath of a disaster. Because we recognize this concern, we have established strategic relationships with emergency response organizations in order to use the best available information to direct critical supplies in the event of a disaster. We are working with FEMA, the Red Cross and the National Guard on the ground to identify areas of need and direct supplies to them as quickly as possible. We recognize that coordinating responses to disasters can be complex and imperfect, but we are doing everything in our power to get the necessary medical supplies to the people that need them.

What are the damages to your members' facilities, and how do they affect security?

Our members are evaluating the damages to their facilities within the earthquake and tsunami damage areas, and can speak to their specific findings. We can say that our members have processes in place to secure their facilities in these instances as a matter of policy, but our individual members would be the best source of information about these specific processes.